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August 3, 2004

Barbara J. LoDico, BS, CIP  
Executive Director, Human Subjects Protection  
University of Medicine & Dentistry of New Jersey - Newark Campus  
University of Medicine & Dentistry of New Jersey - New Brunswick Campus  
65 Bergen St, SSB 1411  
Newark, NJ 07107

**RE: Human Research Subject Protections Under Federalwide Assurances (FWA) 36 & 1861**  
**Activities Involving the Graduation Questionnaire (GQ)**

Dear Ms. LoDico:

The Office for Human Research Protections (OHRP) has reviewed your report of November 31, 2003 regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) involving the above-referenced activities conducted at the University of Medicine & Dentistry of New Jersey (UMDNJ).

OHRP makes the following determinations about the above-referenced activities:

(1) HHS regulations at 45 CFR 46.116 require that procedures for enrolling subjects minimize the possibility of coercion or undue influence. It was alleged that many of the schools that recruit subjects for this research make participation in the research a requirement for graduation from medical school. OHRP acknowledges UMDNJ's statement that UMDNJ does not require completion of the GQ for graduation from medical school, but some students think that it is required. OHRP recommends that medical students be informed that it is not a graduation requirement.

(2) In accordance with HHS regulations at 45 CFR 46.103(b) and 46.109(a), the institutional review board (IRB) must review and approve all non-exempt human subject research covered by an assurance. It was alleged that human subject research involving the GQ was conducted without IRB review.

**Corrective Action:** OHRP acknowledges UMDNJ's statement that UMDNJ will require that student surveys, including the GQ, be reviewed and approved by the appropriate

UMDNJ IRB. UMDNJ is now developing appropriate policies and procedures specific to the administration of student surveys. OHRP also acknowledges that the AAMC intends to seek IRB review of the GQ prior to its next administration.

(3) HHS regulations at 45 CFR 46.116 state that, except as provided elsewhere in the regulations, no investigator may involve a human being as a subject in research covered by the regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. It was alleged that the institutions initiated human subjects research without meeting this requirement.

**Corrective Action:** OHRP also acknowledges that AAMC will provide an opportunity for medical students completing the GQ to provide specific informed consent about whether or not the AAMC may retain their GQ data in a personally identifiable form for research purposes.

(4) HHS regulations at 45 CFR 46.111(a) state that, in order to approve research covered by the regulations, the IRB shall determine that certain requirements are satisfied. It was alleged that this research failed to satisfy the following requirements:

- (a) Risks to subjects are minimized.
- (b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- (c) Selection of subjects is equitable.
- (d) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

OHRP finds that this allegation could not be substantiated.

OHRP finds that the corrective actions above adequately address the concerns raised about the above-referenced activities and are appropriate under the UMDNJ FWAs. As a result of the above determinations, OHRP sees no need for further involvement in this matter.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kristina C. Borrer, Ph.D.  
Director  
Division of Compliance Oversight

cc: Ms. Anna M. Baiata, Director, Newark Campus IRB's, U Med Dentistry NJ - Newark  
Campus  
Mr. Paul Papagni, Director- Institutional Review Board, U Med Dentistry NJ - New  
Brunswick Campus  
Dr. Cheryl Kennedy, Chair, IRBs #1-#4, UMDNJ-Newark  
Dr. Mary Swigar, Chair, IRBs #1-#5, UMDNJ -New Brunswick  
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